

CERTIFICATE OF ELECTRONIC TRANSMISSION

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Date: June 7, 2010 Name: Douglas A. Oguss

Signature: \_\_\_\_\_

Our Case No. 12730/253  
(PA-6087-CON4)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Timothy A.M. Chuter	)	Examiner: Julian W. Woo
	)	
Serial No.: 10/816,780	)	Group Art Unit No.: 3773
	)	
Filing Date: April 2, 2004	)	Confirmation No.: 9975
	)	
For: FLAT WIRE STENT	)	

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir or Madam:

Applicant requests review of the file of the above-identified application, for the reasons stated in the attached sheets. No amendments to the claims are filed with this request. Applicant also files a Notice of Appeal along with this request. No more than five (5) pages are provided.

**I. Background**

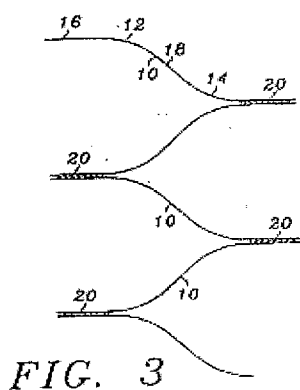
**A. The Rejections**

Claims 12, 14-18 and 22-25 are pending in the application. In the Final Office Action dated February 5, 2010 ("the Final Office Action"), claims 12, 14-18 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,630,829 ("Lauterjung") in view of U.S. Pat. No. 4,830,003 ("Wolff"). Claim 22 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauterjung in view of Wolff, and further in view of U.S. Pat. No. 5,397,355 ("Marin"). Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauterjung in view of Wolff and Marin, and further in view of U.S. Pat. No. 6,221,102 ("Baker"). Claim 24

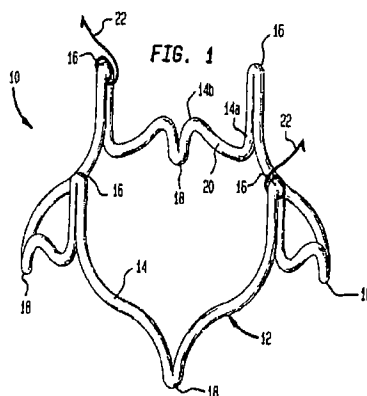
is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauterjung in view of Wolff, and further in view of U.S. Pat. No. 5,282,824 (“Gianturco”).

## B. The Claims

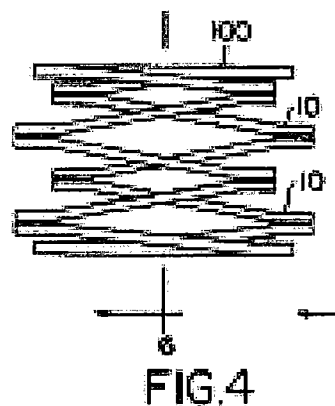
Independent claim 12 requires a stent comprising at least one limb having a cross sectional profile in which at least one segment is flat and straight. Each limb is comprised of two curved portions having opposite directions of curvature, an intermediate straight, flat mid-portion connecting the two curved portions and a short, straight segment at each end. The intermediate straight, flat mid-portion is angled with respect to the short, straight segments at each end in an expanded state. The short, straight segments at each end of the limb are substantially identical to one another. Further, the short, straight segments at each end of the limb are joined to a short, straight segment of an adjacent limb to form a point of attachment, wherein the short, straight segments of adjacent limbs meeting at the point of attachment are substantially parallel to one another in the expanded state. (See, e.g., applicant’s FIG. 3, reproduced below).



Applicant’s FIG. 3



Lauterjung’s FIG. 1



Wolff’s FIG. 4

Independent claims 22-24 are similar to independent claim 12, but the limitation “the intermediate straight, flat mid-portion is angled...” is omitted in claims 22-24. Rather, independent claim 22 requires “the end of each limb has been provided with a barb in order to provide a means of attachment of the stent to the inside of the corporeal lumen.” Independent claim 23 requires “the end of each limb has been provided with a series of serrations in order to provide a means of attachment of the stent to the inside of the corporeal lumen.” Independent claim 24 requires “the end of at least one limb comprising the stent has been provided with a hole as an anchor point for the attachment of a delivery system release mechanism.” Independent claim 25 is similar to claim 12, but is directed to a limb forming a portion of a stent.

The Examiner asserts that Lauterjung discloses some, but not all, of the features recited in pending independent claims 12 and 22-25. For example, the Examiner concedes “Lauterjung does not disclose that the short, straight segments at each end of the limb are substantially identical to one another.” (See Final Office Action at page 3). It is alleged that a combination of Lauterjung with Wolff renders this feature obvious.

## **II. The Outstanding Rejections are Improper**

Applicant respectfully asserts that neither Lauterjung nor Wolff, nor any other reference cited in the Final Office Action, alone or in combination, teaches or suggests a stent (or limb portion forming a stent) with each and every feature recited in independent claims 12 and 22-25.

The Office Action does not set forth a *prima facie* case of obviousness against independent claims 12 and 22-25. The Office Action’s attempted path, while not expressly stated, appears to lie under MPEP Section 2143, which states “[e]xemplary rationales that may support a conclusion of obviousness include: ... (B) Simple substitution of one known element for another to obtain predictable results.” (MPEP 2143). However, the present invention does not present a “simple substitution” of known elements that obtain “predictable results.”

As indicated above, the Examiner concedes that “Lauterjung does not disclose that the short, straight segments at each end of the limb are substantially identical to one another.” (Final Office Action at page 3). However, the Office Action alleges:

[i]t would have been obvious to one having ordinary skill..., in view of Wolff et al., to modify the limbs of Lauterjung, so that the short, straight segments at each end of a limb are substantially identical to one another. Such a modification would allow the stent of Lauterjung to expand into a tubular shape with uniform spacing between segments and/or limbs, while allowing the stent to exert a given, radially-outward force...without undue traumatization of a vessel wall. (*Id.*).

Applicant respectfully submits that there can be no “simple substitution of one known element for another to obtain predictable results,” particularly since Lauterjung resoundingly teaches away from Wolff. Notably, in at least 10 passages of the patent, Lauterjung repeatedly stresses elongated members that curve in two opposite directions, “each said member being curved over substantially its entire extent.” (see, e.g., Lauterjung Abstract; col. 2, lines 31-35 and 42-43; col. 3, lines 25-26; col. 4, lines 7-9; col. 5, line 48 – col. 6, line 6; col. 6, lines 19-20;

col. 9, lines 10-15 and 49-51; claims 1 and 21; FIG. 1 above). Importantly, Lauterjung stresses that “[i]n accordance with the present invention, the hoop strength of a stent has now been significantly increased by replacing the straight legs with legs which are smoothly curved along substantially their entire length and which therefore contribute to the overall hoop strength of the stent.” (See Lauterjung at col. 2, lines 30-35; emphasis added).

Given that Lauterjung stresses the importance of “replacing the straight legs with legs which are smoothly curved along substantially their entire length,” Lauterjung expressly teaches away from a combination with Wolff, which depicts only straight legs (see Wolff FIG. 4, above). Moreover, Lauterjung suggests stents having “straight legs” (such as Wolff) have a lower hoop strength. (see Lauterjung at col. 2, lines 30-37). Thus, one of ordinary skill in the art would clearly not make such a modification that could significantly adversely affect hoop strength.

By contrast, applicant’s claimed stent provides a limb structure that is distinguishable over both Lauterjung and Wolff, both individually and in combination. Moreover, applicant’s stent of independent claims 12 and 22-25 has clinical advantages, noted in the specification, and previously during prosecution, which are neither taught nor suggested by Lauterjung nor Wolff. (see, e.g., applicant’s specification at page 18, lines 2-14; FIGS. 1-5 and 8-10).

In the “Response to Amendment” section, the Examiner even concedes that “Lauterjung teaches away from elongated members that have ‘straight legs,’ like Wolff’s stent.” (Final Office Action at page 6; emphasis added). The Examiner alleges, in a seemingly contradictory follow-up, that “Lauterjung does not teach away from cusps including short, straight segments like Wolff’s stent.” (*Id.*). To the contrary, Lauterjung teaches away from Wolff by showing cusps 16 and 18 that are oriented at different angles, with greater contact between adjacent cusps 16 relative to the adjacent cusps 18. Thus, they are neither both substantially identical, nor substantially both straight. As noted above, Lauterjung teaches away from Wolff in at least 10 passages by noting the importance of elongated members being curved over substantially their entire extent. Moreover, given that hoop strength will be significantly impacted by altering Lauterjung’s limb structure with the structure of Wolff, there would be absolutely no “predictable results” in how Lauterjung’s modified stent would perform.

In sum, the combination of references cited do not involve a “simple substitution of one known element for another to obtain predictable results,” as suggested by MPEP 2143, and there

is no other basis for a *prima facie* case of obviousness in the Final Office Action. Thus, the Final Office Action fails to meet its burden of establishing a *prima facie* obviousness case.

For at least these reasons, independent claims 1 and 12 are allowable over Lauterjung in view of Wolff. Further, neither Marin, Baker nor Gianturco make up for Lauterjung's and Wolff's deficiencies; thus, independent claims 22-24 also are allowable over the references cited.

Claims 14-18 depend from independent claim 11. As explained above, neither Lauterjung nor Wolff, alone or in combination, teaches or suggests all of the features of independent claim 12. Moreover, dependent claims 14-18 recite additional features that further distinguish over the references cited. Accordingly, these claims would not have been obvious to one of ordinary skill in the art in view of the cited references.<sup>1</sup>

## CONCLUSION

For at least these reasons, Applicant requests review of the final rejection in the current application, withdrawal of all of the rejections against the pending claims, and a re-opening of prosecution. Applicant believes that the present claims are patentable and that the application is in a condition for allowance. Accordingly, Applicant respectfully requests that the Examiner grant allowance of the application. The Examiner is invited to contact the undersigned attorney if such communication would expedite the prosecution of this application.

Respectfully submitted,



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Dated: June 7, 2010

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<sup>1</sup> For purposes of the present request, Applicant confines their discussion to the independent claims and to the Lauterjung and Wolff references. If this request is denied, Applicant reserves the right on appeal to argue and present evidence that the features recited in the dependent claims are independently distinguishable over all of the cited references.